

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRANCIS C. SZOKA, and DAVID
LARWOOD,

No. C 02-05524 SI

Plaintiffs,

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW**

v.

MARTIN C. WOODLE, FRANCIS J. MARTIN,
ANNIE YAU-YOUNG, CARL T. REDEMANN,
and ALZA CORPORATION,

Defendants.

In November, 2002, plaintiffs Francis C. Szoka and David Larwood brought this action claiming sole or co-inventorship of the invention claimed in U.S. Patent No. 5,013,556 (“‘556 Patent”). The ‘556 patent, which issued in May, 1991, is titled “Liposomes with Enhanced Circulation Time.” The four individual defendants – Martin C. Woodle, Francis J. Martin, Annie Yau-Young, and Carl T. Redemann – are currently named as the sole inventors. The remaining defendant, Alza Corporation (“Alza”), owns the ‘556 patent.

From January 10 through 18, 2005, the Court took evidence, including live testimony, sworn narrative statements and documentary evidence, on plaintiffs’ inventorship claim. On April 5, 2005, the Court heard closing arguments by both sides. At that hearing, the Court ordered the parties to submit proposed findings of fact on the key credibility issues in the case. The Court has determined that these credibility issues are dispositive of the requested change in inventorship and will therefore limit its factual findings accordingly. This order constitutes this Court’s findings of fact and conclusions of law in accordance with Federal Rule of Civil Procedure 52(a).

1 Plaintiffs must establish their entitlement to correction of inventorship by clear and convincing
2 evidence. This they have not done. After careful consideration of all the evidence, as well as the
3 arguments of counsel, the Court finds that Szoka and Larwood are not the sole inventors or co-inventors
4 of the invention claimed in the '556 Patent. Accordingly, they are not entitled to correction of
5 inventorship pursuant to 35 U.S.C. § 256, to a declaration that plaintiffs are equitable titleholders of the
6 patent, or to compensation and equitable remedies.

8 BACKGROUND

9 Liposomes are microscopic lipid vesicles, which are used for targeted delivery of
10 pharmaceuticals to different cells and organs. Plaintiff Szoka claims that he was the first to discover
11 that incorporating polyethylene glycol lipids (PEG-lipids) into liposomes enhances the liposomes'
12 circulation time *in vivo*. He further claims that his former graduate student, co-plaintiff David Larwood,
13 "successfully synthesized the PEG-lipids molecules, incorporated the molecules into liposomes, tested
14 the modified liposomes in animals, and showed that they circulated for a longer period than did the
15 unmodified liposomes." Third Am. Compl. at ¶ 14.

16 Plaintiffs seek declaratory judgment to correct inventorship under 35 U.S.C. § 256, naming
17 Szoka and Larwood as sole inventors. *Id.* ¶¶ 12-24. They also bring claims for unjust enrichment and
18 a declaration of equitable title in the patent since its issuance. They seek damages, restitution, and other
19 equitable remedies, including an accounting and disgorgement of the approximately \$92 million in
20 profits Alza has earned from the sale of its Doxil® chemotherapy treatment product on the grounds that
21 the sale of Doxil® constitutes use of the invention of the '556 patent. *Id.* ¶¶ 25-29; see also Prayer.

23 FINDINGS OF FACT ON CREDIBILITY ISSUES

24 According to plaintiffs, the evidence at trial established that they conceived of and reduced to
25 practice all of the independent claims of the '556 patent and the features depending from those claims,
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back during the 1979 - 1986 time frame. They contend that Dr. Szoka disclosed the invention to LTI¹ and Cooper-Lipotech² scientists on four occasions: twice at Cooper-Lipotech research meetings, at which defendant Francis Martin was present; once at lunch with Martin near the Cooper-Lipotech offices; and once at his UCSF office. Szoka also testified that he provided Martin with a copy of a 1986 NIH grant application in which he proposed research targeting liposomes to HIV-infected cells.

The Court resolves the main credibility questions raised by the parties, specifically: (1) whether Szoka and Dr. Pedro Huertas should be believed over Martin and Viola Kung on the issue of Szoka's communication of the invention at Cooper-Lipotech meetings; (2) whether Szoka or Martin is more credible on the question of Szoka's alleged communication over lunch "outside the San Francisco laboratory"; (3) whether Szoka or Peter Dehlinger is more credible regarding Szoka's alleged communication to Dehlinger and Dehlinger's response; (4) the credibility of Dr. Yau-Young's testimony about her process of inventing the '556 patent; and (5) whether Szoka and Larwood's testimony about why they did not learn about the '556 patent until 2001 is believable.

1. Szoka's alleged communications to Francis Martin at Cooper-Lipotech meetings

The Court does not find Dr. Szoka credible on the subject of his communications of the invention to Dr. Martin and others at Cooper-Lipotech research meetings. The sole evidence of these disclosures is the testimony of Dr. Szoka himself and Dr. Huertas. Francis Martin and Viola Kung had no recollection of these discussions.³

At trial, Dr. Szoka testified that he communicated plaintiffs' work on pegylated liposomes to one of the defendants, Dr. Francis Martin, at two research meetings held at Cooper-Lipotech, one in 1982

¹LTI is Liposome Technology, Inc., a company founded by plaintiff Szoka and others in 1981 to develop products using liposomes. Undisputed Fact Nos. 19-20.

²Cooper-Lipotech, Inc. was a joint venture formed in about 1981 between LTI and Cooper Biomedical, Inc. According to its Preincorporation Agreement, the purpose of Cooper-Lipotech was to develop a limited number of diagnostic or immunoassay products using liposomes. Its charter specifically excluded uses of liposomes *in vivo*, i.e., for therapeutic purposes. Martin Narr. ¶¶ 6-8.

³ Viola Kung testified that Szoka "may have talked about PEG lipids at Cooper-Lipotech" and "may have given advice to Cooper-Lipotech on their hemagglutination assays." 6 Tr. 837:14-20. However, she also testified that she had no recollection of the communications Szoka describes making at these meetings.

1 and one in 1983. During this period, Dr. Martin was the Technical Director at Cooper-Lipotech, and
2 Szoka was an advisor to the company and a member of the Board of Directors. Szoka Narr. ¶¶ 75-76.
3 In these capacities, they both attended research meetings along with the scientific founders of LTI,
4 Cooper-Lipotech consultants, and Cooper-Lipotech employees, including Dr. Pedro Huertas, who
5 worked there from 1981 to 1983. Huertas Narr. ¶¶ 1-2; 4-12.

6 Szoka testified that, at a research meeting in mid- to late 1982, he disclosed his and Larwood's
7 work on incorporating PEG-lipids into liposomes to this group during a discussion of how to solve a
8 problem with a diagnostic assay. Szoka Narr. ¶¶ 75, 80; Huertas Narr. ¶¶ 6-9. Specifically, Szoka
9 claims to have disclosed that he and Larwood "had synthesized PEG-PE derivatives using PEGs with
10 a molecular weight of 5000 daltons, and had incorporated the PEG-lipid into a liquid composition by
11 the rehyradtion method . . . [and] that he had calculated that up to 20 mole % PEG-lipid derivatives
12 [either saturated or unsaturated] could be incorporated into liposomes." Szoka Narr. ¶¶ 75, 80; Huertas
13 Narr. ¶¶ 6-9; 1 Tr. 93:23-95:20; 2 Tr. 168:20-170:14. Szoka also testified that he told the Cooper-
14 Lipotech group that he and UCSF lab technicians working under him had injected the PEG-PE modified
15 liposomes into mice and observed that blood levels of the pegylated liposomes were higher than that
16 of non-pegylated liposomes. There is no documentary evidence of any such statements. Dr. Huertas
17 corroborated this disclosure in his testimony, and also stated that Szoka discussed targeting the
18 liposomes to specific cells and tissues by attaching ligands, antibodies, and other targeting molecules
19 to pegylated liposomes. Huertas Narr. ¶ 9.

20 According to plaintiffs, the Cooper-Lipotech group did not initially follow his suggestion, and
21 Szoka raised it again at another meeting in January or February 1983, at which Martin and Huertas were
22 also present. At this second meeting, Szoka testified, he described the chemical process ("imidazolid
23 chemistry") by which plaintiffs had prepared and activated the PEG-lipids, provided a sample of a PE-
24 lipid, and shared his protocol and glassware. Szoka Narr. ¶¶ 82-83; 1 Tr. 95:22-97:3.

25 According to plaintiffs, sometime between March and June 1983, Cooper-Lipotech scientists
26 synthesized PEG-lipids and incorporated them into liposomes. Szoka Narr. ¶ 83; 2 Tr. 159:6-163:25.
27 They synthesized PEG-PE using the imidazolid chemistry Dr. Szoka had allegedly described in the
28 research meetings, using 15 mole percent PEG-lipids in the liposome composition. Szoka Narr. ¶ 84;

1 Huertas Narr. ¶ 10. Szoka also testified that, at another Cooper-Lipotech meeting in 1983, he provided
2 a pre-print of a research article by himself and Larwood, which established the chemistry for activating
3 polyethyleneglycol. Szoka Narr. ¶ 85; 1 Tr. 102:3-14; Huertas Narr. ¶ 12; 2 Tr. 194:15-195:14.

4 Defendants contend, and the Court finds, that it is entirely implausible that Szoka made such
5 extensive disclosures concerning therapeutic uses of liposomes at such Cooper-Lipotech meetings.
6 Given the competitive posture of LTI and Cooper Biomedical, there was at least an informal Cooper-
7 Lipotech policy forbidding any discussion of “therapeutics,” or therapeutic (*in vivo*) applications of
8 liposomes, at research meetings in order to avoid any conflicts about intellectual property ownership
9 between Cooper-Lipotech and LTI. This policy was not written, and Francis Martin and Viola Kung
10 testified that they did not know of anyone being reprimanded for violating the policy, 6 Tr. 842:8-23;
11 6 Tr. 883:3-5, but the documents incorporating the joint venture specified that it was only to focus on
12 diagnostic uses of liposomes and was to exclude therapeutic uses.⁴ Given the close quarters shared by
13 the LTI and Cooper-Lipotech personnel, and the obvious value which all the participants placed on the
14 potentially lucrative intellectual property which might be developed by one or the other of the
15 competitors, the Court finds it believable that a serious effort was made to avoid joint discussions of
16 topics, like therapeutic developments, which were not intended to produce joint results. The Court
17 finds Martin and Kung’s denials more reliable than Szoka’s testimony as to the alleged disclosures at
18 Cooper-Lipotech meetings.

19 Defendants contend that Dr. Huertas’ testimony is not reliable, both because he seemed confused
20 at times and admitted to harboring some bias against defendant Alza because he believed that Alza
21 scientists had taken credit for his own work. When asked why he was testifying, Huertas stated that he
22 wanted the Court “to be aware that the work that [he] performed preceded the claim in [the ‘556] patent
23 by several years.” 2 Tr. 171:11-21. While the Court does not make any specific finding based on these
24 admissions, it does not find Dr. Huertas’ recollections of the Cooper-Lipotech meetings over twenty
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26 ⁴Indeed, Dr. Martin testified that Cooper was also interested in therapeutic applications of
27 liposomes, and that there had been “spirited debate” about the appropriate scope of the joint venture,
28 but LTI “had decided to reserve therapeutic applications for itself.” 5 Tr. 788:6-11. Thus the agreement
specifically defined its field to “exclude the uses of liposomes or liposome systems which are directly
or indirectly administered to or in a living animal or human.” Martin Narr., ¶ 8; DTX 1262.

1 years ago to be reliable. Dr. Huerta' surprisingly acute level of detail about Szoka's alleged disclosures
2 in one of the Cooper-Lipotech meetings, see Huertas Narr. at ¶¶ 6-9, contrasts significantly with his
3 vague recollection of other details from the early 1980s, including his memory of his own work from
4 that period and the content of a particular article provided by Szoka at a second Cooper-Lipotech
5 meeting. 2 Tr. 189:2-13; 205:7-16.

6 The Court finds that the testimony of Dr. Martin, which is consistent with that of Dr. Kung, is
7 more reliable than the testimony of Dr. Szoka and Dr. Huertas on these points. Thus, the Court finds
8 that Dr. Szoka did not present his research on pegylated liposomes at the Cooper-Lipotech meetings,
9 as he claims.

10
11 **2. Szoka's alleged communication to Francis Martin "outside the San Francisco laboratory"**

12 The Court does not find Dr. Szoka credible regarding this disclosure. According to Szoka, in
13 late 1983 or early 1984, after another research meeting at Cooper-Lipotech, he and Francis Martin sat
14 eating lunch "outside the South San Francisco Laboratory." 1 Tr. 103:2-3. During this lunch, Szoka
15 claims to have told Martin that his staff at USCF had incorporated between about 1 and 17 mole %
16 PEG-lipids into liposomes, injected them into animals, and observed that there were more pegylated
17 than non-pegylated liposomes in circulation. Szoka claims that Martin responded that did not believe
18 that this method would be useful in humans. In addition, Szoka testified that he later reminded Martin
19 and defendant Woodle about his invention in December 1988, in Szoka's office at UCSF.

20 Defendants flatly deny that the discussion over lunch, disputed by Francis Martin and
21 uncorroborated by any other witness, ever happened or could have happened. Martin testified that (1)
22 he did not remember ever having lunch outside the laboratory and that there was nowhere to sit and eat
23 outside, (2) the only restaurant near Cooper-Lipotech where he ate was too far to walk, and (3) he did
24 not know enough about therapeutic applications of liposomes in 1983-84 to have participated in such
25 a conversation.

26 Plaintiffs do not dispute Martin's statement that there was nowhere to eat outside the building,
27 but have submitted evidence that there was a restaurant nearby, Sandwich Palace. The Court does not
28 consider this evidence particularly salient on the question of credibility, and agrees with defendants that

Szoka's recollection of eating lunch "outside the laboratory" is not corroborated.

On or about October 4, 1986, Szoka sent Martin a copy of his NIH grant proposal for targeting liposomes to HIV-infected cells. Defendants argue that this disclosure undermines plaintiffs' inventorship claim because it is unlikely that, a few years after he allegedly told Dr. Martin how long-circulating pegylated liposomes would work successfully, he sought research funding from NIH to find out whether they would work. The Court also finds it implausible that Dr. Szoka would have made these disclosures in 1982 and 1983, and then applied for research funding in 1984 and 1986 from NIH to determine whether pegylation had any effect on the circulation time of liposomes.

3. Szoka's alleged communications to Peter Dehlinger⁵

Dr. Szoka testified that he first asked Peter Dehlinger, patent counsel to UCSF, Cooper-Lipotech, and LTI, in 1983 to mid-1984 whether an application could be filed for the invention of incorporating PEG-lipids into liposomes to create long circulating liposomes. Szoka Narr. ¶ 89. Then, after a patent ("the '330 patent") was issued to another inventor, Barry Sears, in January 1984, Szoka asked Dehlinger whether his invention of incorporating the PEG-lipids into liposomes to enhance circulation times would be patentable over the Sears patent. Szoka Narr. ¶ 90-91. This second conversation allegedly occurred after a meeting at LTI. 2 Tr. 221:24-222:10. Szoka testified that he gave Dehlinger a copy of the Sears patent or the patent number, and that Dehlinger told him that he did not think it was patentable. Szoka Narr. ¶ 91; Szoka Reb. Narr. ¶ 6-7; 2 Tr. 220:9-11.

Dehlinger testified that he did not recall Szoka telling him about the invention, and that it was inconceivable that he would have provided an opinion on patentability as alleged by Szoka. 4 Tr. 613:23-614:3; 614:20-615:1. According to Dehlinger, he did not give opinions on patentability without complying with certain procedures, which he only did if he received authorization from UCSF. *Id.* at 615:1-6.

The Court finds that Szoka's descriptions of his disclosure to Dehlinger and the patentability

⁵ Defendants argue that Szoka's alleged communication to Dehlinger is irrelevant in the absence of a communication to at least one of the named inventors. Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004).

1 opinion allegedly obtained are entirely implausible. Szoka testified that, although he and Dehlinger
2 discussed the issue after an LTI meeting, he sought the opinion in Dehlinger's capacity as UC's counsel,
3 see 2 Tr. 224:13-19, and Szoka was asking as a UC employee, not an LTI representative, because he
4 "made it clear . . . that it wasn't an LTI issue" but rather that the work had been done at UC. 2 Tr.
5 223:4-15; 228:15-24. Szoka did not give Dehlinger any document or written description of his
6 invention, and thus Dehlinger allegedly opined that the invention was unpatentable without reviewing
7 any materials other than the Sears patent. See 2 Tr. 221:21-222:10; 223:16-20.

8 The Court finds it unlikely that Dehlinger would have been able to provide a patent opinion with
9 this scant information. In addition, it also finds implausible that Dehlinger would have exposed himself
10 to a blatant conflict of interest by answering Szoka's question without better clarifying their respective
11 affiliations with respect to the proposed invention. As defendants argue, even if the Court believes
12 Szoka that both he and Dehlinger put their UC hats on for purposes of this conversation, the alleged
13 communication would therefore be a disclosure to a UC attorney, not to the defendants in this case.

14 Plaintiffs contend that they impeached Dehlinger, as follows: Dehlinger testified that Szoka
15 would not have asked him to prepare a patent application for UC that Szoka paid for initially, but later
16 assigned to the University. Plaintiffs successfully demonstrated that Dehlinger had filed and prosecuted
17 a prior patent application, for which invoices were sent by Dehlinger's law firm to Szoka while Szoka
18 was abroad, and which was later assigned to UCSF. 4 Tr. 634:15-636:7; 637:13-17; 638:5-25. The
19 impeachment of Dehlinger on this issue does not undermine the Court's finding that Dehlinger's
20 testimony was generally truthful. The Court finds that the scenario described by Szoka was not credible.

21
22 **4. Dr. Yau-Young's testimony**

23 Dr. Yau-Young testified that she conceived of her invention independently of the plaintiffs, and
24 specifically that she did not learn about any work by Szoka or Larwood on pegylated liposomes before
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1 she wrote a July 1987 memo about her concept.⁶ 5 Tr. 682:3-11. She also testified that she did not
2 discuss her idea with anyone, including Francis Martin, before writing her July 1987 memo. Id.

3 Dr. Yau-Young's work during the relevant period was on developing long circulating liposomes
4 using "GM1" liposomes, or "Stealth liposomes," work into which LTI put a great deal of effort. Martin
5 Narr. at ¶ 14; Yau-Young Narr. at ¶ 18; 5 Tr. 803:1-3. According to Yau-Young, she conceived of the
6 idea of using PEG to increase circulation time in 1986, after reading a paper by Dr. Abuchowski about
7 pegylated proteins, and she communicated this idea to Dr. Anthony Huang at a July 1987 meeting of
8 the Formulation Group at LTI. Yau-Young Narr. at ¶¶ 20-22. She then submitted a written research
9 proposal, and recorded the idea in her notebook in December 1987. Yau-Young Narr. at ¶¶ 23, 25.

10 Yau-Young's conception is well-documented, and the Court finds her description entirely
11 credible. Plaintiffs argue that Yau-Young's description of events is not credible because she interacted
12 with and reported to Francis Martin at LTI and because scientists in her group, the Formulation Group,
13 and Martin's Research Group, were aware of one another's work. Plaintiffs also contend that her
14 recollection of her initial conception in 1986 is too vague to be reliable. The Court disagrees on both
15 points: the level of interaction among LTI employees does not discredit Yau-Young's description of
16 how she thought of the idea, nor does her inability to clearly recollect what happened in 1986 undermine
17 her description of the communication and documentation of that conception in 1987. Accordingly, the
18 Court finds that Dr. Yau-Young arrived independently at her conception of the invention contained in
19 the '556 patent.

20 Notably, plaintiffs' case hinges on the alleged communications to defendant Martin. Plaintiffs
21 did not even attempt to establish that Szoka discussed his invention with any of the other three
22 inventors, each of whom testified that their inventions were their own. Dr. Yau-Young testified that she
23 did not obtain any part of her ideas about pegylated liposomes from Dr. Szoka or anyone else at LTI.
24 Dr. Redemann stated that he obtained a technique for activating PEG using carbonyl di-imidazole from
25 his prior experience at the Dow Chemical Company, that this method would have been familiar to most
26 chemists in the 1980s, and that his activation technique was different from Szoka and Larwood's.

27 ⁶ In addition, she testified that she had never heard of David Larwood before this lawsuit. 5 Tr.
28 682:12-17.

1 Plaintiffs introduced no evidence that Dr. Woodle had information about Szoka's invention, and Woodle
2 testified that Szoka never told him about his work with pegylated liposomes.

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4 **5. Szoka and Larwood's credibility regarding the delay in filing suit**

5 It is not disputed that LTI scientists spent a great deal of time and effort attempting to develop
6 long-circulating liposomes from 1985 until 1988, using Stealth liposomes instead of pegylated ones.
7 5 Tr. 801:3-803:1. According to Szoka's testimony, although he had previously communicated his
8 conception of using pegylated liposomes to increase circulation time during 1983 and 1984, and
9 although he sat on the Scientific Advisory Board of LTI, he said nothing further during this period,
10 despite the struggles of LTI scientists to create viable long-circulating liposomes. The Court finds it
11 implausible that Szoka allowed his alleged conception to lie fallow during this gap in time, while the
12 LTI scientists around him pursued a different strategy – with his apparent knowledge and without
13 success. Either Francis Martin and the other LTI scientists did not know about long-circulating
14 pegylated liposomes during this time (because Szoka never communicated the idea to them), or Dr.
15 Szoka himself did not know or believe at this time that pegylated liposomes would be long-circulating.
16 The latter explanation is more likely, particularly because Szoka did not assign anyone in his lab to
17 continue working on his alleged pegylated liposome project after Larwood left in 1983, did not publish
18 anything on the subject, and changed his own area of focus to the gangliosides used in the Stealth
19 liposomes. 2 Tr. 250:19-251:1; 249:19-24; 247:12-24. In any event, these facts undermine Szoka's
20 testimony about either his conception of the idea, its communication to defendants, or both.

21 On October 20, 1989, defendants Woodle, Yau-Young, Martin, and Redemann filed an
22 application for the '556 patent, which was handled by Peter Dehlinger. According to plaintiffs, they
23 were unaware of the patent application, and Dr. Szoka did not become aware of his rights in the '556
24 patent until mid to late 2001, when he was contacted by defendant Alza Corporation to be an expert in
25 another patent case. Szoka had a potential conflict of interest because he had co-founded a company
26 recently acquired by Valentis, the parent company of the plaintiff in that case, and so he declined.
27 Valentis' counsel mentioned the '556 patent to Szoka, and he obtained a copy and reviewed it.

28 Defendants argue that plaintiffs either knew or should have known of the '556 patent at least ten

1 years earlier, in 1992, when Szoka filed another patent application (the ‘669 patent) which states:
2 “[v]arious types of activators for PEG and monomethoxy PEG have been described in U.S. Pat. No.
3 5,013,556 to Woodle et al.” Joint Pretrial Conf. Stat., Undisputed Fact No. 38.⁷ In addition, they argue
4 that Larwood, who had gone on to become a patent lawyer, must have known about the ‘556 patent by
5 1993, because in that year he took over prosecution of the ‘669 patent application and filed an
6 amendment specifically correcting the reference to the ‘556 patent in the ‘669 patent application. Szoka
7 acknowledged reviewing the application, but he testified that he focused only on the description of the
8 invention, and Larwood stated that his work on the 1993 amendment involved minor typographical
9 changes, and he did not read the entire patent or the references.

10 These explanations are implausible because Szoka’s 1992 patent application states that
11 “[v]arious types of activators for PEG and monomethoxy PEG have been described in U.S. Patent No.
12 5,013,556 to Woodle et al.” In addition, the Court agrees with defendants that Larwood should or would
13 have reviewed the prior art in filing the 1993 amendment, consistent with his duty to do so, and that his
14 law firm submitted to the patent office a list of references and stated that the ‘556 patent “may be
15 material to examination of this application.” The front page of the ‘556 patent would have provided
16 notice that the patent disclosed “Liposomes with Enhanced Circulation Time,” and particularly when
17 coupled with Dr. Woodle’s name, would have indicated to Szoka that LTI might have patented long-
18 circulating pegylated liposomes.

19 Therefore, the Court finds not credible the testimony that neither Szoka nor Larwood reviewed
20 the ‘556 patent in connection with Szoka’s 1992 patent application, and accordingly finds that plaintiffs
21 had actual knowledge of the patent in September 1992.

22 CONCLUSIONS OF LAW

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25 ⁷ The Court does not find that plaintiff Szoka knew or should have known about defendants’
26 patent because of his familiarity with the work being done by defendant Woodle on pegylated liposomes
27 at LTI, his knowledge of LTI’s pegylated liposome product Doxil, or his sophistication in the area of
28 patents and biotechnology companies. The record does not clearly establish Szoka’s awareness of these
facts, and thus they are not the basis for the finding that plaintiffs should have known or at least
suspected that LTI had a patent on long-circulating pegylated liposomes.

Inventorship

The inventors named in the '556 patent, Drs. Woodle, Martin, Yau-Young, and Redemann are "presumed to be correct." Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997). To establish correction of inventorship, plaintiffs bear the burden of establishing inventorship by clear and convincing evidence. Id. at 979-80. For sole inventorship, plaintiffs must show that they conceived of each and every limitation in all of the claims in the '556 patent. Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998); Trovan, Ltd. v. Sokymat S.A., Irori, 299 F.3d 1292, 1302 (Fed. Cir. 2002). In addition, plaintiffs must also provide "corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention." Burroughs Wellcome Co. v. Barr Labs, Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994). For co-inventorship rather than sole inventorship, plaintiffs need only show contribution to one claim of the patent.

The Court finds that plaintiffs have not established inventorship by clear and convincing evidence, nor have they presented corroborating evidence of a contemporaneous disclosure that would have enabled one skilled in the art to make the invention. As discussed above, the Court does not find Dr. Szoka credible on the subject of the four communications to Dr. Francis Martin, the alleged communications to Peter Dehlinger, or the subject of when Szoka learned about the '556 patent. Moreover, Szoka and Larwood's oral testimony about their conceptions of the invention rest on their post hoc review of notebooks containing details of various experiments, and is insufficient to establish contemporaneous recognition of the invention, rather than simply "nunc pro tunc" conception. Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 593-94 (Fed. Cir. 1994).

Co-Inventorship

Plaintiffs have also brought a claim for joint inventorship, seeking to be added to the patent in this capacity. A claim for joint inventorship requires a showing of collaboration between plaintiffs and defendants. 35 U.S.C. § 116; Eli Lilly & Co. v. Aradigm Co., 376 F.3d 1352, 1359 (Fed. Cir. 2004). Plaintiffs did not pursue this claim at trial; their proof focused solely on Szoka's alleged disclosures of the communications to one of the defendants. Indeed, the proof at trial was to the contrary: Dr. Yau-Young was solely responsible for the invention in the broadest claims, and it is undisputed that she and

1 Dr. Szoka never worked together; Drs. Woodle, Redemann, and Martin worked on more specific aspects
2 of the patent claims in the LTI laboratories.

3
4 **Damages and Doctrine of Laches**

5 Because the Court finds that plaintiffs have not met their burden of establishing inventorship by
6 clear and convincing evidence, they are not entitled to damages. In addition, the Court finds that the
7 doctrine of laches applies to plaintiff's claims. For the doctrine to apply, there must be (1) unreasonable
8 and unexcused delay and (2) material prejudice to the defendants as a result. Advanced Cardiovascular
9 Sys., Inc. v. Scimed Life Sys., Inc., 988 F.2d 1157, 1163 (Fed. Cir. 1993). There is a presumption of
10 laches if the delay is six years or more. Id.

11 The Court has found that plaintiffs knew or should have known about the subject matter of the
12 '556 patent at least by 1992, at the time of Dr. Szoka's application for the '669 patent. This action was
13 filed in 2002. Thus, defendants are entitled to the presumption of laches, and plaintiffs have not rebutted
14 this presumption. The Court has found Szoka and Larwood not credible on the subject of why they did
15 not discover the '556 patent and its subject matter in 1992.

16 Accordingly, the Court finds that no correction of inventorship is required.

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18 **IT IS SO ORDERED.**

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20 Dated: March 6, 2006

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22 SUSAN ILLSTON
23 United States District Judge
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